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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,646	07/19/2005	Johannes Fridolin Schlapfer	8932-1208-999	1676

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NEW YORK, NY 10017-6702

EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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07/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,646

Applicant(s)

SCHLAPFER ET AL.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-20, 22, 23, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Saurat (US Pat. 6,099,528).

Saurat disclose an apparatus for the dynamic stabilization of bones or bone fragments, in particular spinal vertebrae, comprising a longitudinal support (Fig. 9, ref. 25), the longitudinal support having a first end, a second end, and a uniform stiffness extending from the first end to the second end (column 2, lines 59-65), the longitudinal support being sized and configured to be fixed to the vertebra, the longitudinal support is plastically deformable between a first stable shape state and a second stable shape state by application of a prespecified bending force, the longitudinal support remaining flexible within predetermined limits while in the first and second stable shape states. The longitudinal support is elastically deflectable when clamped at one end while in the first or second stable shape states. With regards to the statement that the rod is elastically deflectable, the longitudinal support has a varying stiffness across the support (column 1, lines 36-38), which implies that at least portions of the rod are flexible (*i.e.* less stiff). Since the rod is flexible, it is elastically deformable. The longitudinal support is stable with respect to anatomically usual longitudinal shear forces

and with respect to anatomically usual transverse shear forces. The longitudinal support is substantially stable when subjected to anatomically usual torsion. The longitudinal support is in the shape of a flat band or strip. The definition of "strip" according to The Merriam-Webster Online Dictionary is "a long narrow piece of material." The longitudinal support of Saurat is a long narrow piece of material, as seen in Fig. 9, ref. 25. The longitudinal support is rotationally symmetrical (Fig. 3). The longitudinal support is hollow (column 4, lines 64-66). The longitudinal support comprises a plastically deformable core made of metal (Fig. 9, ref. 26) (column 3, lines 63-65) encased in a human-tissue-compatible plastic member (column 3, lines 65-67 and column 4, lines 1-2) that provides flexibility within a stable shape state. The longitudinal support is dimensioned such that within the predetermined limits its surface stress is always below the dynamic breaking stress. The core and the plastic member are always below the respective dynamic breaking stress. The core is encased in more than one layer (column 5, lines 3-5). The longitudinal support can be fixed. The apparatus further comprises longitudinal support-connecting-means, operative to connect at least two support sections to one another (column 4, lines 24-30). The longitudinal-support-connecting means comprising two oppositely situated support-receiving openings (Fig. 12, openings near ref. 35 and ref. 36) into each of which an end section of the support (Fig. 12, ref. 35 and 36) can be inserted (Fig. 12) and fixed by a clamping screw or similar clamping element (Fig. 12, ref. 34) (column 4, lines 24-31). The apparatus further comprises bone anchoring means (Fig. 13, ref. 37) comprising longitudinal-support-receiving openings (Fig. 13, openings in refs. 37, top and bottom, through which

ref. 19 passes) that can be spaced at variable axial distances from the opposite distal end, so that the longitudinal support can be adjusted to a correspondingly different distance from the vertebra. The core is in the form of a flat band or strip, with a width smaller than or equal to the corresponding dimension of the longitudinal support (Figs. 3, 4, and 5, refs. 6, 8, and 11). The core can be considered to be a strip since it is a long narrow piece of material (Fig. 9, ref. 26). The core is rotationally symmetrical (Fig. 3, ref. 6), with either a constant diameter or a diameter that varies along the length of the longitudinal support (column 2, lines 43-55). The diameter of the core, at least in sections, is enlarged or reduced in a stepwise manner (column 2, lines 43-55) (Fig. 1, step near where ref. 2 points), the transitions of the stepwise manner in the region of a step are constructed so as to reduce stress. The transitions of the stepwise manner in the region of a step are rounded (since the core can be round, e.g. Fig. 3, ref. 6) to reduce stress. The rotationally symmetrical core is circular (Fig. 3, ref. 6). The longitudinal support comprises a hollow rod (column 2, lines 43-47). The predetermined limits comprise the elastic flexion range.

Saurat discloses an apparatus comprising: a longitudinal support member (Fig. 9, ref. 25) having a uniform stiffness from a first end thereof to a second end thereof (column 2, lines 59-65, the longitudinal support member being sized and configured to engage at least two vertebrae, the longitudinal support member including a deformable core (Fig. 9, ref. 26) made of metal (column 3, lines 63-67) and a bio-compatible plastic member (column 3, lines 65-67)(column 4, line 1) sized and configured to encase said core, the longitudinal support member being deformable between a first stable state and

Art Unit: 3733

a second stable state by application of a bending force, the longitudinal support member remaining flexible in the first and second stable states; wherein the longitudinal support is flexible in a first direction but not in a second direction (since the longitudinal support is flexible along the axis transverse to the longitudinal axis, but not along the longitudinal axis itself) . The first direction is flexion and extension.

With regards to statements of intended use and other functional statements (e.g. "...can be fixed to the vertebra...", "...plastically deformable from a first stable shape state into a second stable shape state by application of a prespecified bending force...", "...remaining flexible within predetermined limits while in the first and second stable shape states...", "...provides flexibility within a stable shape state...", "...the longitudinal support is stable and unyielding...", "...its surface stress is always below the dynamic breaking stress...", "...can be fixed...", "...operative to connect..." etc.), they do not impose any structural limitations on the claims distinguishable over the device of Saurat, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saurat (US Pat. 6,099,528).

With regard to claim 2, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the elastically deflectable longitudinal support of Saurat with the rod being elastically deflecatable by an angle of 5 to 12 degrees, over a length corresponding to the spacing of two adjacent vertebrae, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claim 24, it would have been obvious to have constructed the longitudinal support being elastically deflectable by a first distance when clamped at one end while in the first or second stable shape states, the first distance being between about 2 cm to about 5 cm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saurat (US Pat. 6,099,528) in view of Kahn et al. (US Pat. 3,938,198).

Saurat discloses the claimed invention except for the metal core comprising titanium or a titanium alloy.

Kahn et al. disclose a rod (Fig. 1, ref. 13) with a metal core (column 2, lines 52-55) comprising titanium (column 2, lines 52-55) surrounded by a different material (column 2, lines 44-52), the core being made out of titanium in order to provide a core which is strong, lightweight, and resistant to attack by body fluids (Kahn et al., column 2, lines 52-55).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have made the core of Saurat from titanium as taught by Kahn et al, in order to provide a core which is strong, lightweight, and resistant to attack by body fluids (Kahn et al., column 2, lines 52-55).

Response to Arguments

Applicant's arguments filed 05/02/2007 have been fully considered but they are not persuasive.

With regard to Applicant's argument that Saurat does not disclose a longitudinal support that remains flexible within predetermined limits while in the first and second stable shape states, the Examiner respectfully disagrees. Any material will remain somewhat flexible even after being placed in a stable shape; this flexibility will be within predetermined limits, since the physical properties of the materials that are being used

Art Unit: 3733

in the device will only allow a certain amount of flexibility before the structure of the device is permanently deformed or broken. The points at which the material is deformed or broken can be considered to be the "limits".

With regard to Applicant's argument that Saurat does not disclose a uniform stiffness along the length of the rod, the Examiner respectfully disagrees. Saurat discloses in column 2, lines 59-65 that the stiffness can vary in a radial plane rather than along the longitudinal axis of the device. This would yield a rod that has a uniform stiffness along the longitudinal axis of the rod.

With regard to Applicant's argument that Saurat does not disclose a rod that is flexible in one direction and not in another direction, the Examiner respectfully disagrees. The rod of Saurat is flexible along an axis transverse to the longitudinal axis, but not in a direction parallel to the longitudinal axis. Therefore Saurat discloses one direction that the rod is flexible in and a second direction the rod is not flexible in.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 3733

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

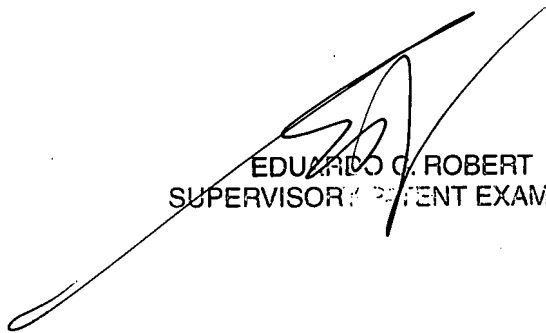
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Application/Control Number: 10/542,646

Page 10

Art Unit: 3733

JLC

A handwritten signature in black ink, appearing to be the initials 'JLC'.A large, stylized handwritten signature in black ink, likely belonging to Eduardo C. Robert.

EDUARDO C. ROBERT
SUPERVISOR / PATENT EXAMINER